

AUG - 4 1999

David L. Rose  
Merck & Co., Inc.  
P.O. Box 2000  
Rahway, NJ 07065-0907

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,199,569

## NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,199,569, which claims the human drug product STROMEKTOL® and the method of use of STROMEKTOL®, is eligible for patent term extension under 35 U.S.C. § 156.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 1,291 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of July 10, 1998 (63 Fed. Reg. 37398). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,055) + 263 \\ &= 1,291 \text{ days}\end{aligned}$$

Since the regulatory review period began August 17, 1990, after the patent issue date (April 22, 1980), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made by the Food and Drug Administration. Accordingly, the testing phase of the regulatory review period has not been reduced by the period of time suggested by applicant.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	4,199,569
Granted	:	April 22, 1980
Original Expiration Date	:	October 3, 1997

Applicant	:	Chabala et al.
Owner of Record	:	Merck & Co., Inc.
Title	:	Selective Hydrogenation Products of C-076 Compounds and Derivatives Thereof
Classification	:	424/180
Product Trade Name	:	STROMEKTOL® (ivermectin)
Term Extended	:	1,291 days
Expiration Date of Extension	:	April 16, 2001

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents  
Box Patent Ext.  
Washington, D.C. 20231

By FAX: (703) 308-6916  
Attn: Special Program Law Office

By hand: Crystal Plaza Four, Suite 3C23  
2201 South Clark Place  
Arlington, VA 22202

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

---

Karin Tyson  
Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: David T. Read  
Acting Director Regulatory Policy Staff, CDER  
Food and Drug Administration  
1451 Rockville Pike, HFD-7  
Rockville, MD 20852

RE: STROMEKTOL®  
FDA Docket No.: 97E-0061